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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,678	03/10/2004	Fiona Patricia Carney	CL/V-32902A	4167

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PATENT DEPARTMENT
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EXAMINER	
APANIUS, MICHAEL	
ART UNIT	PAPER NUMBER
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/797,678	CARNEY ET AL.
	Examiner	Art Unit
	Michael Apanius	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64 and 84-91* is/are pending in the application.

4a) Of the above claim(s) *2-4,18-20,34-36,50-52 and 85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-17,21-33,37-49,53-64,84 and 86-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed on 11/1/2006. The amendments to claims 1, 5, 9-14, 17, 21, 25-28, 31, 33, 37, 41-46, 49, 53, 57-60, 63 and 84; the amendments to the specification; the replacement drawing sheet; and the new drawing sheet are acknowledged. Currently, claims 1-64 and 84-91 are pending, while claims 2-4, 18-20, 34-36, 50-52 and 85 are withdrawn.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method steps must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The amendment filed 11/1/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the changes to the applications incorporated by reference on pages 8, 13 and 23 appear to introduce new matter because only the provisional applications were originally incorporated by reference. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

5. Claims 11, 15, 25, 32, 43, 57, 64 and 86 are objected to because of the following informalities: at line 2, of claims 11, 25, 43, 57 and 86, it appears that "its" should be --estrogen--; at claim 15, line 1, "methd" is misspelled; and at line 2 of claims 32 and 64, it appears that --from the onset of menses-- should be added after "day 6". Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 5-8, 9-17, 21-24, 25-33, 37-49, 53-62, 84 and 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catt et al. (US 6,451,619) in view of Abreu (US 6,544,193).

8. Catt discloses a method (column 4, lines 11-20) for determining the fertility status of a current ovulation cycle of a female human, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance (LH, estradiol and progesterone: column 9, lines 27-33) to female fertility; and (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said female human, wherein the step of monitoring is performed by periodically collecting a tear fluid (column 3, lines 60-62) from the female human and then determining the tear concentration of said hormone.

9. In regards to claim 9, the first collecting of tear fluid in the current cycle is made during the interval spanning days 1 to 7 from the onset of menses (column 5, lines 7-29), one of which will correlate with the cessation of menses.

10. In regards to claim 10, the first collecting of tear fluid in the current cycle is made during the interval spanning days 1 to 7 from the onset of menses which includes at least 3 days following the onset of menses.

11. In regards to claim 11, the hormone can be estrogen and wherein a significant increase in estrogen tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period (column 4, lines 42-47).

12. In regards to claim 12, the hormone can be LH and wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, following the cessation of menses, indicates that the female human will no longer be fertile four days hence (column 9, lines 38-50).

13. In regards to claim 13, the hormone can be progesterone (column 9, line 33), wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.

14. In regards to claims 14 and 15, estrogen and progesterone can be monitored to determine the status of a menstrual cycle of the female human (column 9, lines 27-33).

15. In regards to claim 16, the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the teaer concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is inherently indicative of the onset of the fertile period (see Baird et al. listed under "OTHER PUBLICATIONS").

16. In regards to claim 17, the steps are performed one per day for at least several days preceding and following ovulation (column 30, lines 27-28).

17. In regards to claims 31 and 32, a base concentration value or signal for said hormone in the current cycle is establishes on day 5 or 6 from the onset of menses (column 5, lines 7-23).

18. In regards to claims 33 and 49, Catt discloses a birth control method that involves avoiding exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation (column 6, lines 35-45).

19. In regards to claim 84, Catt discloses testing fertility of a female non-human mammal (column 3, line 53 and column 4, line 12).

20. Corresponding claims are similarly disclosed as noted above.

21. Catt does not expressly disclose wearing a contact lens to collect tear fluid.

22. Abreu teaches wearing a contact lens over an 8 hour period and collecting tear fluid at the end of the 8 hour work day for the purpose collecting and analyzing tear fluid in a continuous, comfortable, undisturbed, accurate and low-cost manner (column 42, lines 49-52; column 50, lines 50-64). Abreu further teaches using a soft contact lens (column 96, lines 11-14). Abreu also teaches using a contact lens having a core material (column 41, lines 61-63) that contains a receptor for specifically binding a hormone (column 17, lines 50-51).

23. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a contact lens as taught by Abreu in the method of

Catt in order to collect and analyze tear fluid in a continuous, comfortable, undisturbed, accurate and low-cost manner.

Response to Arguments

24. Applicant's arguments filed 11/1/2006 have been fully considered but they are not persuasive.

25. Applicant argues that Catt and Abreu are non-enabling disclosures because the references do not disclose nor appreciate that there exists a direct correlation between serum and tear concentration of hormones of significance in relation to the fertility status of a female and/or to sex differentiation or dysfunction. In response, it is respectfully submitted that Catt and the combination of Catt and Abreu do provide an enabling disclosure. Catt discloses measuring the concentration in body fluid of hormones of significance in relation to fertility status as noted above in the rejection. Catt discloses measuring hormone concentrations in a general body fluid but primarily focuses on one example body fluid, urine (i.e. see abstract). Catt further discloses alternative body fluids such as tears (column 3, line 62). The disclosure would enable one of ordinary skill in the art to alternatively apply the methods of Catt to the alternative body fluids, such as tears, also disclosed by Catt. Furthermore, Abreu expressly teaches means for detecting hormone concentrations in tears. Therefore, the combination of Catt and Abreu is even further enabled by the specific teachings of Abreu to measure hormone concentrations in tears.

26. Applicant further argues that the cited art does not disclose or suggest minimizing or eliminating biological concentration variability of said hormone in the tear fluid by wearing the contact lens on the eye for at least 30 minutes nor anything about a contact lens having a core material that is prepared from a composition containing a receptor which binds specifically said hormone. In response, it is respectfully noted that Abreu teaches wearing a contact lens for at least 30 minutes as noted above in the rejection. By wearing a contact lens for 30 minutes, biological concentration variability will be minimized or eliminated. Furthermore, the enzymes used in the contact lens chemically react with a hormone (column 141, lines 9-20) and therefore contain a receptor to bind specifically the hormone.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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